

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

NOMB

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Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 16 and 17, 2000, 8:30 a.m. to 5:30 p.m.

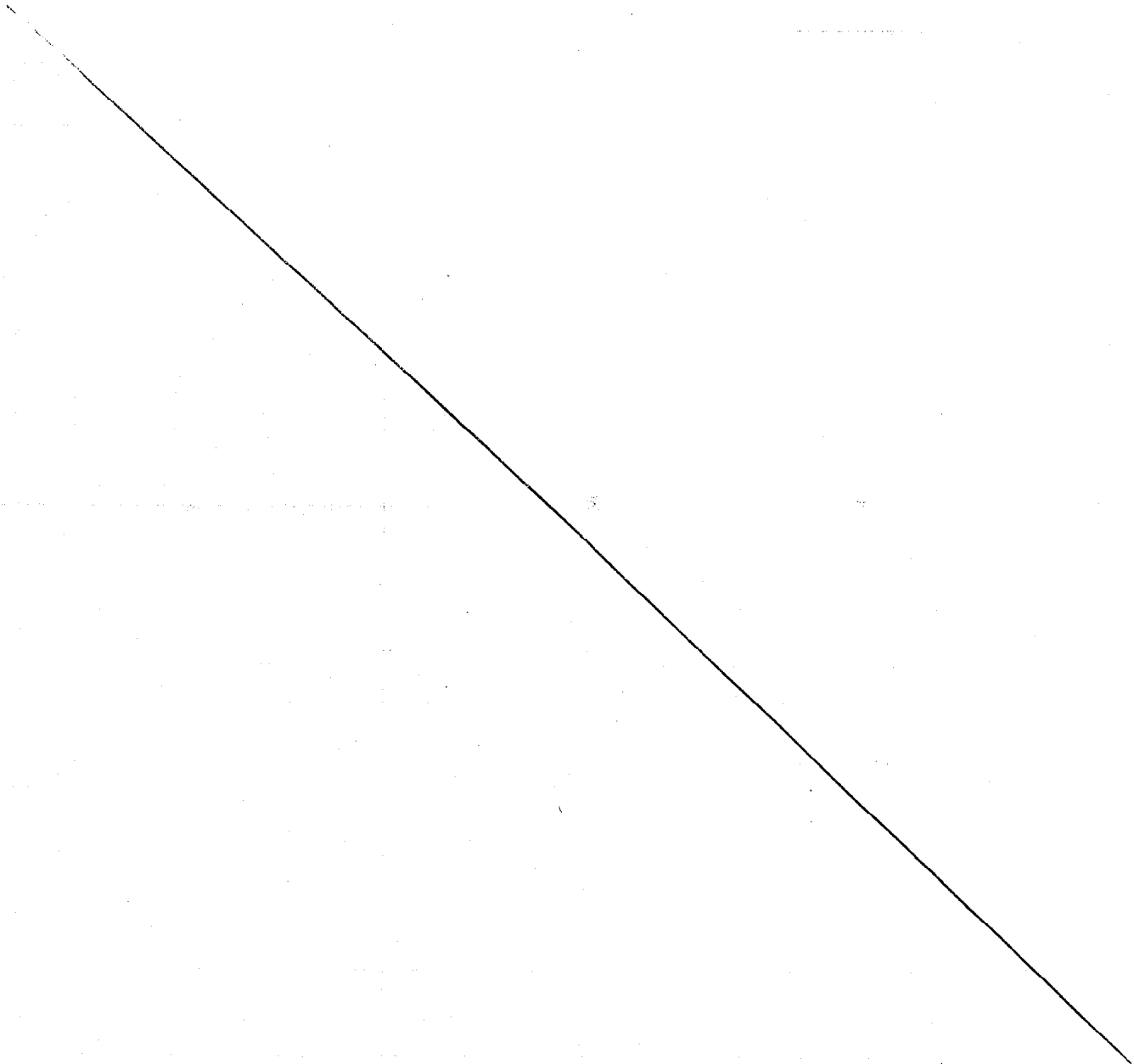
Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 16 and 17, 2000, the committee will meet to discuss the following issues related to gene therapy clinical trials: (1) Product characterization, (2) preclinical models, and (3) long term followup.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 9, 2000. Oral presentations from the public will be scheduled between approximately

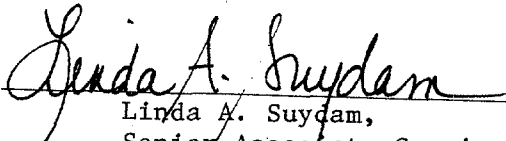
1 p.m. and 1:30 p.m. on November 16, 2000, and from 9 a.m. to 9:30 a.m. on November 17, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 10/18/00
October 18, 2000


Linda A. Suydam,
Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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